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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.			TALMAN, JAMES R	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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ED

<b>Office Action Summary</b>	<b>Application No.</b> 10/812,884	<b>Applicant(s)</b> KANAYAMA ET AL.	
	<b>Examiner</b> James R. Talman	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 26-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Receipt of amendment dated 8/1/2007 is acknowledged. Claims 24 and 25 are cancelled, claims 1-23 and 26-30 are pending.

### ***Terminal Disclaimer***

2. Although the amendment stated that a Terminal Disclaimer had been filed, same was NOT received.

### ***Response to Arguments***

3. Applicant's arguments filed 8/1/2007 have been fully considered but they are not persuasive.
4. On page 18 of applicants' remarks, it is argued that Kruger (US Patent Application 2003/0069491) does not disclose gaps between elements.
5. The Examiner respectfully disagrees, citing gaps between elements in Figure 3 of Kruger.
6. On page 18 of applicants' remarks, it is argued that it would not have been obvious to a person having ordinary skill in the art to place waveguides in the gaps between elements.
7. The Examiner respectfully disagrees, citing a waveguide (84) placed between elements in the handheld unit disclosed by Kruger (86-1 through 86-8 in Figure 7).
8. On page 19 of applicants' remarks, it is argued that it would not have been obvious to a person having ordinary skill in the art at the time of the invention to

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integrate waveguides with the detector because the purpose of Kruger was to provide a detector rotatable with respect to the waveguides.

9. The Examiner respectfully disagrees, citing the waveguide (84) placed in a fixed position between detector elements in the handheld unit disclosed by Kruger (86-1 through 86-8 in Figure 7).

### ***Claim Objections***

10. Claim 11 is objected to because of the following reason:

In claim 11, the status identifier is indicated as "Currently Amended", but no changes are indicated relative to the original claim. Therefore, the correct status identifier should be "Original."

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As per claim 26, in part (d) of the claim, "detecting an ultrasound image" is confusing. Examiner suggests changing "detecting" to --displaying--.

Further as per claim 26, in part (c) of the claim, "displaying the photoacoustic signal" is confusing. Examiner suggests changing " displaying" to --detecting--.

### ***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-3, 5, 6, 12-17, 20-23, and 26-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 9, 10, 12, 16, 19, 27, 31,32, and 38-40 of U.S. Patent No. 6979292. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application and the patent claims cover common subject matter and achieve the same end result of imaging a subject using a

combination of electroacoustic and ultrasonic modalities and because the claims of the instant application are obvious variants of the '292 patent.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-23, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruger (US Patent Application Publication 2003/0069491).

As per claims 1, 2, 3, and 4, Kruger discloses a non-invasive imaging apparatus comprising: a light-generating unit (electromagnetic energy from an external source, paragraph 30), light irradiation and waveguide means (18, 84) for guiding and radiating light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) at a plurality of wavelengths (2-12 centimeters, paragraph 4), a plurality of vertically and horizontally arrayed electroacoustic transducer elements with gaps between elements (24, 32, Figure 3), transmission means for transmitting Ultrasonic waves (52, 54), reception means for generating a reception signal from the ultrasonic waves (52, 56), signal processing means for generating volume data by processing a reception signal corresponding to acoustic waves generated in the subject by light radiated from the irradiation unit (46, 48), and signal processing means for generating volume data about a subject morphology by processing a reception signal

corresponding to echoes generated in the subject upon transmission of the ultrasonic waves (US imaging system, 52). Kruger further discloses a waveguide (84) discretely arranged between arrayed electroacoustic transducer elements in a handheld unit (86-1 through 86-8; see also Figure 7), surrounded by eight elements. Kruger does not explicitly disclose using optical fiber for the waveguide means and does not explicitly disclose a plurality of waveguides in the handheld unit. As stated in the last Office Action, optical fibers are a well-known waveguide means for infrared and visible light electromagnetic radiation. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the invention of Kruger to use optical fiber as the waveguide means in order to investigate the subject properties at infrared and visible wavelengths. Furthermore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to use a plurality of waveguides between the detector elements in order to obtain more uniform and/or more powerful illumination. Furthermore, the exact number of elements surrounding the waveguide is an obvious design choice and is not given patentable weight.

As per claims 5 and 6, Kruger further discloses scanning means (scanning system, paragraph 37), accomplished by rotating the waveguides (18) and detector array (24) to multiple angular positions (paragraph 31) and further discloses generating a reception signal corresponding to acoustic waves generated by irradiation of the light (TACT system and receiver, 46 and 48), from electrical signals from a predetermined number of transducer elements (24, 32) near an end portion of a waveguide (Figure 1).

As per claim 7, and as applied to claim 2 above, Kruger further discloses radiating light beams (electromagnetic radiation, see abstract) from not less than two optical fibers (at least eight waveguides, Figure 6A) whose end portions are spaced apart by not less than a predetermined distance.

As per claim 8, and as applied to claim 7 above, Kruger further discloses generating a reception signal corresponding to acoustic waves generated by irradiation of the light (TACT system and receiver, 46 and 48), from electrical signals from a predetermined number of transducer elements (24, 32) near an end portion of an optical fiber (waveguide, Figure 1).

As per claim 9, and as applied to claim 2 above, Kruger further discloses simultaneously radiating light (synchronized electromagnetic radiation, paragraph 16) from a plurality of end portions of optical fibers (waveguides, Figure 1-; eight positions, Figure 6).

As per claim 10, and as applied to claim 9 above, Kruger further discloses generating a reception signal from electrical signals (TACT system and receiver, 46 and 48), from a predetermined number of transducer elements (24, 32) near an end portion of an optical fiber (waveguide, Figure 1).

As per claims 11 and 12, Kruger further discloses alternately (separately) performing (Simultaneously, or as a separate imaging modality, paragraph 37) the irradiation of light and the transmission of ultrasonic waves.

As per claim 13, Kruger further discloses forming a 2-dimensional image (paragraph 10). Furthermore, forming a 2-dimensional image from a 3-dimensional



volume of data inherently requires selecting a single slice from the 3-dimensional volume.

As per claims 14 and 15, Kruger further discloses displaying (display, 50) living body function image data (TACT data, paragraph 37) and morphology image data (ultrasound image, paragraph 37), with said morphology image data superimposed on (overlaid, paragraph 37) said living body function image data on the display. Kruger does not explicitly disclose displaying the images side by side. It would have been obvious to a person having ordinary skill in the art at the time of the invention to display

As per claim 16, Kruger discloses an imaging method comprising: irradiating a subject to be examined with light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) containing a specific wavelength component (2-12 cm, paragraph 4), receiving acoustic waves using a plurality of two-dimensionally arranged electroacoustic transducer elements (24, 32), transmitting ultrasonic waves in a plurality of directions (54), receiving echoes from the ultrasonic waves (56), generating volume data about a tissue morphology (US imaging system, 52), and generating volume data about a living body function on the basis of the acoustic waves (TACT system and receiver, 46 and 48). Kruger further discloses a waveguide (84) between arrayed electroacoustic transducer elements in a handheld unit (86-1 through 86-8; see also Figure 7). Kruger does not explicitly disclose using optical fiber for the waveguide means and does not explicitly disclose a plurality of waveguides in the handheld unit. As stated in the last Office Action, optical fibers are a well-known waveguide means for infrared and visible light electromagnetic radiation. It would have

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been obvious to a person having ordinary skill in the art at the time of the invention to modify the invention of Kruger to use optical fiber as the waveguide means in order to investigate the subject properties at infrared and visible wavelengths. Furthermore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to use a plurality of waveguides between the detector elements in order to obtain more uniform and/or more powerful illumination.

As per claim 17, Kruger further discloses sequentially radiating light (electromagnetic radiation) from said plurality of radiators by rotating the apparatus in order to collect signals from a sequence of multiple angular positions paragraph 31).

As per claims 18 and 19, Kruger further discloses simultaneously radiating light (synchronized electromagnetic radiation, paragraph 16) from a predetermined number of discrete positions (eight positions, Figure 6).

As per claim 20, Kruger further discloses alternately (separately) performing (Simultaneously, or as a separate imaging modality, paragraph 37) the irradiation of light and the transmission of ultrasonic waves.

As per claims 21-23, Kruger discloses a subject-information imaging apparatus comprising: irradiation means for irradiation a subject to be examined with light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides), ultrasonic transmission means for transmitting ultrasonic waves (54), a plurality of two-dimensionally arrayed electroacoustic conversion means for receiving an acoustic wave (transducer elements 24, 32, Figure 3), first image data generating means on the basis of the acoustic wave (TACT system and receiver, 48, and 46)

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generated in the subject upon the irradiation of light, second image data generating means based on the ultrasonic waves (56), display means (display, 50) for displaying the first image data and the second image data, wherein the ultrasonic wave transmission means is partly commonly used as the electroacoustic conversion means (the sensors on array 24 may be used for conventional ultrasound imaging of the subject tissue, paragraph 37), and wherein the display means displays the first image data and the second image data on the same monitor (an ultrasound image of the tissue may be overlaid with the TACT-generated image, paragraph 37). Kruger further discloses a plurality of vertically and horizontally arrayed electroacoustic transducer elements with gaps between elements. Kruger does not explicitly disclose arraying the elements in the form of a grid array. Grid arrays are an old and well known technique of arranging sensor elements in an array. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the invention of Kruger to place the elements in a grid array for ease of manufacture of the handheld unit disclosed in Kruger (Figure 7).

As per claim 29, the phrase "for diagnosing disease such as breast cancer" is intended use language and is not given patentable weight because it is not further reflected in the body of the claim. Kruger discloses an apparatus comprising: a light-generating unit (electromagnetic energy from an external source, paragraph 30), light irradiation and waveguide means (18, 84) for guiding and radiating light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) at a plurality of wavelengths (1-12 centimeters, paragraph 4), first electroacoustic

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conversion means (two-dimensional array of transducer elements 24, 32), first image data generating means (46, 48), transmission means for transmitting ultrasonic waves (52, 54), second image data generating means on the basis of the second electroacoustic conversion means (US imaging system, 52), and a display means for displaying the first image data and the second image data (an ultrasound image of the tissue may be .. overlaid with ...the TACT-generated image, paragraph 37). Kruger further discloses a plurality of vertically and horizontally arrayed electroacoustic transducer elements with gaps between elements (24, 32, Figure 3). Kruger does not explicitly disclose using a plurality of optical fibers for the waveguide structure and does not disclose a second electroacoustic conversion means for converting components of the ultrasonic waves transmitted by the ultrasonic wave transmission means but, rather, uses the first electroacoustic conversion means for converting both the acoustic waves and the ultrasonic waves.

As stated in the last Office Action, optical fibers are a well-known waveguide means for infrared and visible light electromagnetic radiation. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the invention of Kruger to use optical fiber as the waveguide means in order to investigate the subject properties at infrared and visible wavelengths. Furthermore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to use a plurality of waveguides between the detector elements in order to obtain more uniform and/or more powerful illumination.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Kruger to use separate electroacoustic conversion means as it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art, *Nerwin v. Erlichman*, 168 USPQ 177, 179. Furthermore, separate arrays of transducer elements would avoid the need for filtering of the two signals.

As per claim 30, the phrase "for determining a distribution of the concentration of an analyte" is intended use language and is not given patentable weight because it is not further reflected in the body of the claim. Kruger discloses an apparatus comprising: a light-generating unit (electromagnetic energy from an external source, paragraph 30), light irradiation and waveguide means (18, 84) for guiding and radiating light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) at a plurality of wavelengths (paragraph 4), first electroacoustic conversion means (two-dimensional array of transducer elements 24, 32), first image data generating means (46, 48), transmission means for transmitting ultrasonic waves (52, 54), on means (86), second image data generating means on the basis of the second electroacoustic conversion means (US imaging system, 52), and a display means for displaying the first image data and the second image data (an ultrasound image of the tissue may be overlaid with ...the TACT-generated image, paragraph 37). Kruger further discloses a plurality of vertically and horizontally arrayed electroacoustic transducer elements with gaps between elements (24, 32, Figure 3). Kruger does not explicitly disclose using a plurality of optical fibers for the waveguide structure and does not explicitly disclose a

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second electroacoustic conversion means for converting components of the ultrasonic waves transmitted by the ultrasonic wave transmission means but, rather, uses the first electroacoustic conversion means for converting both the acoustic waves and the ultrasonic waves.

As stated in the last Office Action, optical fibers are a well-known waveguide means for infrared and visible light electromagnetic radiation. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the invention of Kruger to use optical fiber as the waveguide means in order to investigate the subject properties at infrared and visible wavelengths. Furthermore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to use a plurality of waveguides between the detector elements in order to obtain more uniform and/or more powerful illumination.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Kruger to use separate electroacoustic conversion means as it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. Furthermore, separate arrays of transducer elements would avoid the need for filtering of the two signals.

17. Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruger (US Patent Application Publication 2003/0069491) in view of Chou (US Patent No. 6049728).

As per claims 26 and 28, Kruger discloses a method of imaging the human breast (radiation in a breast, paragraph 27) comprising: a probe having two-dimensionally arrayed ultrasound imaging elements (Figure 7), irradiating the tissue with light pulses (pulsed radiation, paragraph 9) to generate a photoacoustic signal, detecting the photoacoustic signal using ultrasound transducers (24, 32), and generating and displaying an ultrasound image and a photoacoustic image (an ultrasound image of the tissue may be .. overlaid with ...the TACT-generated image, paragraph 37), using common acoustic and ultrasound detection elements (86). Kruger further discloses a waveguide (84) irradiation unit integrated with electroacoustic transducer elements in a handheld unit (86-1 through 86-8; see also Figure 7).

Kruger does not explicitly disclose separate acoustic and ultrasonic detection elements but, rather, uses same set of detection elements to detect both signals and does not explicitly disclose irradiating the tissue with light having wavelengths within an absorption spectral band of hemoglobin. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Kruger to use separate electroacoustic conversion means as it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. Furthermore, separate arrays of transducer elements would avoid the need for filtering of the two signals.

Chou discloses using a wavelength corresponding to an absorption spectral band of hemoglobin (electromagnetic energy at wavelengths corresponding to the absorption characteristics of the analyte, column 3, lines 13-15; monitor .... Hemoglobin, column 4,

line 37). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the invention of Kruger by using a wavelength corresponding to an absorption spectral peak of hemoglobin in order to generate images with high specificity to the presence of blood within the breast.

18. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kruger (US Patent Application Publication 2003/0069491) in view of Chou (US Patent No. 6049728), and further in view of Diab et al (US Patent Application Publication 2003/0097049).

As per claim 27, and as applied to claim 26 above, the Kruger/Chou combination, as applied to claims 26 above, discloses all the elements of the claimed invention except that it does not explicitly disclose using a wavelength of light in the spectral range between 530 nm and 1300 nm. Diab et al discloses a relative absorption spectrum of oxygenated and de-oxygenated hemoglobin from 300 nm to 1000 nm showing various absorption peaks and valleys, etc. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the combination of Kruger/Chou to use wavelengths in the range from 530 nm to 1300 nm, as this range is very close to the spectral absorption range for hemoglobin disclosed in Diab et al and therefore wavelengths in this range could be chosen to maximize the signal from the hemoglobin or to provide best contrast between oxygenated and de-oxygenated hemoglobin.

### ***Conclusion***



19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James R. Talman whose telephone number is 571-270-3029. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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James R Talman  
Examiner  
Art Unit 3737

Jrt

  
ELENI MANTIS MERCADER  
SUPERVISORY PATENT EXAMINER